Contact Person: Gail M. Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314 or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will participate in a general scientific discussion of allogeneic transplantation with a focus on haplo-identical transplantation and other high risk transplantations.

Procedure: On November 13, 1998, from 8:30 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 6, 1998. Oral presentations from the public will be scheduled between approximately 8:30 a.m and 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 6, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On November 13, 1998, from 8 a.m. to 8:30 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to discuss issues related to past and pending biologics license applications and investigational new drug applications.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 22, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–28906 Filed 10–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 16, 1998, 8:30 a.m. to 5:30 p.m., and on November 17, 1998, 8 a.m. to 5 p.m.

Location: Holiday Inn, Kennedy Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 16, 1998, the committee will discuss: (1) New drug application (NDA) 20–886 Panretin® (alitretinoin) Gel 0.1 percent, Ligand Pharmaceuticals Inc., indicated for the first-line topical treatment of cutaneous lesions in patients with acquired immune deficiency syndrome (AIDS)-related Kaposi's sarcoma; and (2) NDA 21–041 DepoCyt™ (cytarabine liposome injection), DepoTech Corp. indicated for the intrathecal treatment of lymphomatous meningitis. On November 17, 1998, the committee will discuss the labeling of NDA 17–970/S–040 Nolvadex® (tamoxifen citrate), Zeneca Pharmaceuticals, and whether the indication should be ''for reducing the short term incidence of breast cancer'' in women at high risk of developing the disease or ''as a preventative agent for the reduction of breast cancer in women at high risk for developing the disease. The term prevention indicates a reduction in the incidence (risk) of invasive breast cancer over the period of the NSABP P–1 trial, and does not necessarily imply that the initiation of breast cancer has been prevented or that the tumors have been permanently eliminated * * *.''

Procedure: On November 16, 1998, from 8:30 a.m. to 5:30 p.m., and on November 17, 1998, from 8 a.m. to 1:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 9, 1998. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9 a.m., and between approximately 1:45 p.m. and 2 p.m. on November 16, 1998, and between approximately 8:15 a.m. and 8:45 a.m. on November 17, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 9, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation. After the scientific presentations, a 30-minute open public session will be conducted for interested persons who have submitted their request to speak by November 9, 1998, to address issues specific to the submission or topic before the committee.

Closed Committee Deliberations: On November 17, 1998, from 1:30 p.m. to 5 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss personal conflict of interest issues.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 22, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–28905 Filed 10–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Product and Clinical Development of Tumor Vaccines; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following public workshop: Product and Clinical Development of Tumor Vaccines. This workshop, which is cosponsored by FDA and the National Institutes of Health, will assist FDA and the interested public in developing policies and standards for product and clinical development for tumor vaccines.

Date and Time: The public workshop will be held on Thursday, December 10,